IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Adam S. Cantor et al.	Art Unit	: 1615
Serial No.	: 09/965,610	Examiner	: Isis A. D. Ghali
Filed	: September 26, 2001	Conf. No.	: 8132
Title	: COMPOSITION FOR TRANSDERMAL DELIVERY OF FENTANYL		

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF

In response to the Notice of Non-Compliant Appeal Brief mailed July 14, 2010, please make the following corrections.

The Notice objected to the Status of Claims section on the ground that the section failed to indicate which claims were being appealed. Please substitute the following section for the originally filed Status of Claims section to address the objection.

(3) Status of Claims

Claims 1-9, 16-18, 28-29, 35-36, and 39-103 are pending. Claims 48-51 and 55-91 have been withdrawn. Claims 1-5, 35, 39-42, 52-53, and 91-97 stand rejected under 35 USC § 102(b) over Miranda et al., US 5,474,783 ("Miranda"). Claims 1-9, 16-18, 28-29, 35-36, 39-47, 52-54, and 92-103 stand rejected under 35 USC § 103 over Miranda in view of Garbe et al., WO 96/08229 ("Garbe"). Appellants hereby appeal the rejections of claims 1-9, 16-18, 28-29, 35-36, and 39-103.

The Notice also objected to the "Summary of Claimed Subject Matter" section on the ground that the section failed "to identify which independent claims are being discussed in a separate statement for those claims." Please substitute the following section for the originally filed Summary of Claimed Subject Matter section to address the objection. Please note that the citations refer to the pages and numbered paragraphs appearing in the published counterpart of the application (US 2002/0119187).

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(5) Summary of Claimed Subject Matter

Claims 1-9, 16-18, 28-29, 35-36, 39-47, 52-54, and 92-103 are being appealed. Claims 1, 35, 36, 54, 92, 95, and 98 are independent.

Claim 1 is directed towards a transdermal drug delivery composition (p. 1/[0017]) consisting essentially of: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group (p. 1/[0018]-[0019]); and (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer (p. 1/[0020]); (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition (p. 1/[0021]); and, optionally, (c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof (p. 2/[0036]-[0037]). The composition is free of undissolved fentanyl (p. 2/[0036]).

Claim 35 is directed towards a transdermal drug delivery composition (p. 2/[0030]) consisting essentially of: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of iso-octyl acrylate, 2-ethyl hexyl acrylate, butyl acrylate, and cyclohexyl acrylate (p. 2/[0031]); and (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer, where the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof (p. 2/[0032]); (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition (p. 2/[0036]); and, optionally, (c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof (p. 2/[0036]-[0037]). The composition is free of undissolved fentanyl (p. 2/[0036]).

Claim 36 is directed towards a transdermal drug delivery composition (p. 2/[0030]) consisting essentially of: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of iso-octyl acrylate, 2-ethyl hexyl acrylate, butyl acrylate, and cyclohexyl acrylate (p. 2/[0031]); and (ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer, where the B monomers are selected from the

group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof (p. 2/[0032]); (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition (p. 2/[0036]); and, optionally, (c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof (p. 2/[0036]-[0037]). The composition is free of undissolved fentanyl (p. 2/[0036]).

Claim 54 is directed towards a transdermal drug delivery composition (p. 2/[0030]) consisting essentially of: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of iso-octyl acrylate, 2-ethyl hexyl acrylate, butyl acrylate, and cyclohexyl acrylate (p. 2/[0031]); and (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer, where the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof (p. 2/[0032]); (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition (p. 2/[0036]); and (c) a delivery enhancing adjuvant selected from the group consisting of methyl laurate, tetraglycol, and mixtures thereof (p. 3/[0039]). The composition is free of undissolved fentanyl (p. 2/[0036]).

Claim 92 is directed towards a transdermal drug delivery composition (p. 1/[0017]) consisting essentially of: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group (p. 1/[0018]-[0019]); and (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer (p. 1/[0020]); and (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition (p. 1/[0021]). The composition is free of undissolved fentanyl (p. 2/[0036]).

Claim 95 is directed towards a transdermal drug delivery composition (p. 2/[0030]) consisting essentially of: (a) a copolymer comprising (i) one or more A monomers selected from the group consisting of iso-octyl acrylate, 2-ethyl hexyl acrylate, butyl acrylate, and cyclohexyl acrylate (p. 2/[0031]); and (ii) one or more ethylenically unsaturated B monomers

copolymerizable with the A monomer, where the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof (p. 2/[0032]); and (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition (p. 2/[0036]). The composition is free of undissolved fentanyl (p.2/[0036]).

Claim 98 is directed towards a transdermal drug delivery composition (p.2/[0030])consisting essentially of: (a) a copolymer comprising (i) about 40 to about 95% by weight of one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group (p.2/[0031]); and (ii) about 5 to about 55% by weight of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer (p.2/[0032]); (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition (p.2/[0036]); and, optionally, (c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof (p.2/[0036]-[0037]). The composition is free of undissolved fentanyl (p.2/[0036]).

Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:/July 26, 2010/_____

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